

REMARKS

Status of the Claims

Claims 1-23 and 35-46 were previously cancelled. By this amendment, claims 24, 26-29, 31, 32, and 47 have been amended and claims 59-62 have been added. Claims 24-34 and 47-62 remain pending and under consideration.

Independent claim 24 has been amended to recite a self-expandable stent having a single-component structure formed from a single material. Support for this amendment can be found throughout the as-filed specification and drawings, including for example, FIGs. 1-3 and paragraphs 36-44 of the corresponding published application (U.S. Patent Application Publication No. 2004/0098105, hereinafter "the '105 Application").

Claim 31 has been amended to recite a pair of cuffs that are adapted to engage a tissue located adjacent to the waist and disposed between the pair of cuffs to substantially limit longitudinal movement of the self-expanding stent. Support for this amendment can be found throughout the as-filed specification and drawings, including for example, FIG. 6(f) and paragraphs 37 and 51 of the '105 Application.

Claim 32 has been rewritten in independent form. Claims 26-29 have been amended to depend from independent claim 24. Claim 47 has been amended to depend from independent claim 32.

New claims 59 and 60 recite a single material and single component stent, respectively, support for which can be found in paragraphs 36-44 and FIGs. 1-3 of the '105 Application. New claims 61-62 recite forces applied by the cuffs, support for which can be found in paragraphs 37 and 51 and FIG. 6(f) of the '105 Application.

Accordingly, no new matter has been added.

35 U.S.C. § 103(a) Rejection

Claims 24-34 and 47-58 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,599,299 to Weaver et al. ("Weaver") in view of U.S. Patent No. 5,366,504 to Andersen et al. ("Andersen"). See Office Action, p. 2. The Office alleges that Weaver substantially discloses the elements of independent claims 24 and 31 except for a self-expanding stent, an outer catheter, and a distal tip having a proximally facing surface. See *id.* at p. 3. The Office also alleges that Andersen discloses such a stent, an outer catheter, and a distal tip, and that it would have been obvious combine the disclosures of Weaver and Andersen in order to provide, *inter alia*, "secure anchoring of the stent into the wall of the body lumen and prevent axial movement of the stent." *Id.* at p. 4.

Applicant respectfully disagrees with and traverses this rejection at least because Weaver and Andersen, taken alone or in combination, fail to disclose, teach, or suggest, each and every limitation recited by amended independent claims 24, 31, and 32.

Amended claim 24 recites a "self-expandable stent having a single-component structure formed from a single material." Weaver does not disclose a self-expanding stent and Andersen's stent is formed "of multiple filaments or strands of different materials." Andersen, col. 1, ll. 55-56.

Claim 31 has been amended to further define the cuffs to distinguish over the prior art of record. The stents disclosed by Weaver and Andersen are configured for placement within pre-existing anatomical passages, such as biliary tubes or blood vessels. Of these stents that are flared, the ends are radially expanded to provide stent

anchoring within the passage. Such anchoring relies predominantly on radial forces between the stent ends and the surrounding passage.

Figures 7b and 7d of Andersen show a stent 30 with flared ends 82, 82' placed within an aortic aneurysm, wherein ends 82, 82' expand radially to contact the passage wall. See Andersen, col. 9, l. 52 - col. 10, l. 36.

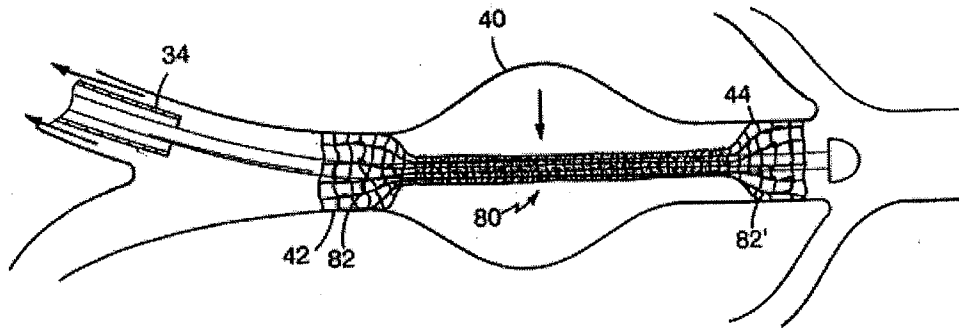


FIG. 7b

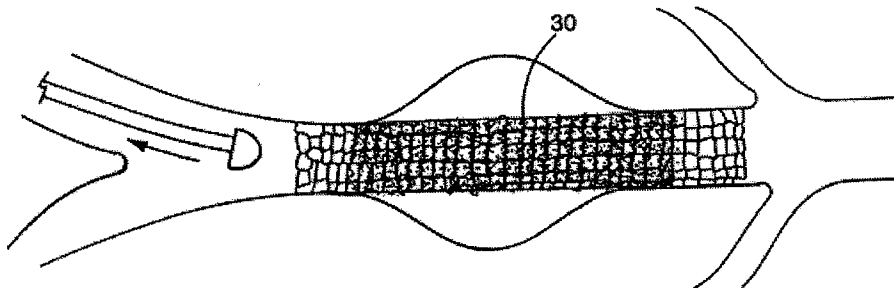
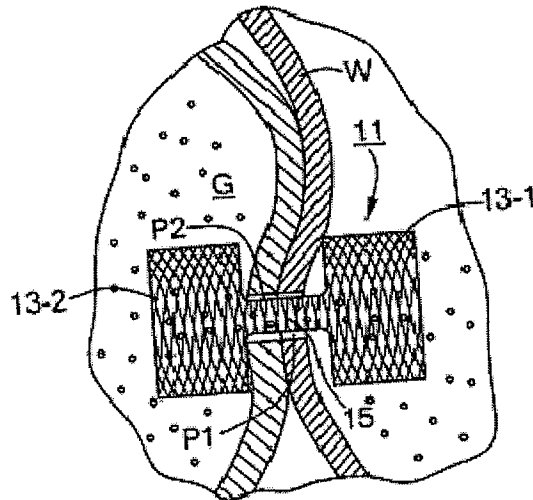


FIG. 7d

Consequently, Andersen's stent 30 is anchored predominantly through the action of radial forces applied between ends 82, 82' and the tissue surrounding ends 82, 82'. In contrast to Andersen's radial forces, the self-expanding stent according to claim 31 has cuffs to engage tissue therebetween to limit longitudinal movement.

While ends 82, 82' of the Andersen device are surrounded by tissue, cuffs 13-1, 13-2 according to an exemplary embodiment of the invention generally extend into the cavities of the stomach and pseudocyst, as shown below.



Because the inward facing surfaces of cuffs 13-1, 13-2 contact the walls of the stomach and pseudocyst, cuffs 31-1, 13-2 of this embodiment generally apply longitudinal forces to the tissue in order to prevent stent migration. See '105 Application, para. [0037] and [0051].

Thus, while ends 82, 82' of the Andersen device rely on radial forces for stent anchoring, cuffs 13-1, 13-2 of the exemplary inventive embodiment rely on longitudinal forces. These longitudinal forces are applied to tissue that is generally located adjacent to waist 15 and between cuffs 13-1 and 13-2 of stent 11. As shown in Figs. 7b and 7d above, Andersen lacks such tissue.

Amended independent claim 32 recites a self-expanding stent "wherein said waist has an expanded diameter of about 8-10 mm, each of said cuffs has an expanded diameter of about 15 mm, and wherein each of said waist and said cuffs has a length of about 5-10 mm." The Office alleges that Andersen discloses a stent with such

dimensions at col. 4, ll. 39-44. See Office Action, p. 3. However, Andersen's stent ranges in length from 40-80 mm, while the claimed length ranges from 15-30 mm. See Andersen, col. 4, ll. 39-44. Applicant respectfully submits that the Office has failed to establish a *prima facie* case of obviousness because neither reference, alone or in combination, discloses, teaches, or suggests each and every element of claim 32.

Such a relatively "short" stent according to an exemplary embodiment of the invention may be dimensioned to accommodate two or more layers of tissue between the cuffs. Thus, the length of the waist of a short stent may be of the order of several millimeters. Neither Weaver nor Andersen disclose or suggest such stent dimensions.

Moreover, use of a relatively "short" stent as recited by claim 32 would likely not provide adequate stenting of biliary tracts because such a short stent may migrate or not adequately maintain biliary patency. Thus, one of ordinary skill, relying on Weaver or Andersen, would have no reason to use a relatively short self-expanding stent.

For at least the foregoing reasons, Applicant respectfully submits that pending claims 24-34 and 47-58 are distinguishable over the prior art and in condition for allowance. Thus, Applicant respectfully requests that the Office withdraw the 35 U.S.C. § 103(a) rejection of these claims.

Applicant also submits that new claims 59-62 are allowable at least due to their dependency from amended claim 31.

Conclusion

In view of the foregoing remarks, Applicant submits that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art


references cited against this application. Applicant therefore requests the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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By:  [#](58 Oct 3)(Matthew Van Eman)
Jeremy P. Bond
Reg. No. 59,682
(617) 452-1659
for